

Application No. 10/609,120
Atty Dkt No. 11187-00016 (Endow-1)
Reply to Office Action of October 6, 2004

REMARKS

In the Office Action under reply, claims 1-32 have been examined and have been rejected as follows:

1. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,886,024 to Vallee et al. (claims 1-32);
2. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,679,806 to Zheng et al. (claims 1-3, 6-13, 16-23, 26-28, 31, and 32);
3. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,783,189 to Pei et al. (claims 1-3, 6-13, 16-23, 26-28, 31, and 32);
4. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,960,908 to Ito et al. (claims 26-28, 31, and 32);
5. Under 35 U.S.C. §102(b) as anticipated by French Patent No. FR 2190411 to Blaise et al. (claims 126-28 and 31-32);
6. Under 35 U.S.C. §102(b) as anticipated by Jagdish et al. (claims 26, 27, 29, and 30-32); and
7. Under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention (claims 1-6 and 17-24).

With the above amendments, claims 1-3, 5, 7, 8, 13, 15, 17, 18, 23, 25-28, and 30 have been amended. Thus, claims 1-32 remain pending in the application. The Examiner's rejections are addressed, in part, by the above-amendments and are otherwise traversed by the arguments presented below.

THE AMENDMENTS TO THE CLAIMS

Claims 1, 7, 17, and 26 have been amended to exclude R₁ heterocyclic groups and R₇ alkoxy groups and to provide that R₅ cannot be hydroxy when R₁, R₂, R₃, R₄, R₆, and R₇ are all

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hydrogen. Support for the proviso is found in the express recitation of compound 40 on page 17 of the specification.

Claims 1-3, 7, 8, 13, 17, 18, 23, and 26-28 have been amended to correct various typographical and grammatical errors and to provide proper antecedent basis for the dependent claims, e.g., the term "unbranched" has been replaced with "straight chain," the term "hydroxide" has been replaced with "hydroxy," and the term "a" has been inserted before "mammal" in the preamble of claims 7 and 8.

The term "amino" has been added into the definition of R_5 in claims 1, 2, 7, 8, 17, 18, 26, and 27. Support for this amendment can be found in dependent claims 3, 13, 23, and 28.

Claims 5, 15, 25, and 30 have been amended to clarify that R_1 is (C_1-C_6) hydroxyalkyl or (C_5-C_{10}) carboxyalkyl and to properly depend directly from the appropriate independent claim. Support for this amendment can be found in the claims as originally presented.

The term " (C_5-C_{10}) carboxyalkyl" has been inserted into the definition of R_5 in claims 2, 8, 18, and 27. Support for this amendment can be found in dependent claims 5, 15, 25, and 30.

Claims 26 and 27 have been amended to specify that R_3 is hydrogen.

No new matter has been added.

THE REJECTION UNDER 35 U.S.C. §102(B) OVER VALLEE ET AL.

The Examiner has rejected claims 1-32 over the disclosure in the Abstract and column 15 of Vallee et al. asserting that the compounds depicted therein anticipate the presently claimed invention. Applicants respectfully disagree.

Each of the compounds described in Vallee et al. possess and a hydroxy group in the R_5 position of the presently pending claims as well as an alkyl, hydroxyalkyl, or carboxyalkyl group in the R_1 position. That is, the Vallee et al. compounds contain both R_5 hydroxy moieties and R_1 alkyl, hydroxyalkyl, or carboxyalkyl moieties. In contrast, compounds having both R_5 hydroxy

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moieties and R₁ alkyl, hydroxyalkyl, or carboxyalkyl moieties are excluded from the scope of the presently pending claims.

As the Examiner will see, the currently pending claims require one of two versions of the compounds of the invention. The first of these two versions, version A, is recited in claims 1, 3, 6, 7, 9-13, 16, 17, 19-23, 26, 28, 31, and 32, while the second version, version B, is recited in claims 2, 4, 5, 8, 14, 15, 18, 24, 25, 27, 29, and 30.

Version A and version B differ in the following two ways:

1. Version A claims allow hydroxy substituents in the R₅ position, while version B claims do not.
2. Version B claims allow alkyl, hydroxyalkyl, or carboxyalkyl moieties substituents in the R₁ position, while version A claims do not.

Thus, there are no pending claims in the present application that include compounds having both R₅ OH moieties and R₁ alkyl, hydroxyalkyl, or carboxyalkyl moieties. Given that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), it is clear that the compounds disclosed in Vallee et al., do not anticipate the subject matter of the presently pending claims. The rejection is in error and its reconsideration and withdrawal are in order and are respectfully requested.

THE REJECTION UNDER 35 U.S.C. §102(B) OVER ZHENG ET AL.

The Examiner has rejected claims 1-3, 6-13, 16-23, 26-28, 31, and 32 over the disclosure of the compounds of Fig. 1 in Zheng et al. asserting that the compounds depicted therein anticipate the presently claimed invention. Applicants respectfully disagree.

Zheng et al. disclose some of the previously known analogs of daidzin. Applicants point out that each of the disclosed analogs contains a hydroxy group at the R₅ position and either:

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1. a heterocyclic group at the R₁ position, i.e., daidzin, genistin, 6"-O-acetyl daidzin, 6"-O-acetyl genistin, 6"-O-malonyl daidzin, and 6"-O-malonyl genistin,
2. a heterocyclic group at the R₂ position, i.e., puerarin, or
3. an alkoxy group at the R₇ position, i.e. glycitein.

As discussed above, the B version of the presently pending claims does not allow for hydroxy at the R₅ position. Given the presence of an R₅ hydroxyl in each Zheng et al. compound, claims 2, 8, 18, and 27 cannot be anticipated by the disclosure in Zheng et al.

With respect to the remaining rejected claims, i.e., claims 3, 6, 7, 9-13, 16, 17, 19-23, 26, 28, 31, and 32, Applicants wish to point out that, as amended, independent claims 1, 7, 17, and 26 include neither R₁ heterocyclic groups nor R₇ alkoxy groups. Furthermore, none of the claims have ever included R₂ heterocyclic groups.

Given that the compounds disclosed in Zheng et al. do not fall within the scope of the pending claims, they do not provide a basis for a rejection under 35 U.S.C. §102(b). Reconsideration and withdrawal of the rejection over Zheng et al. is accordingly requested.

THE REJECTION UNDER 35 U.S.C. §102(B) OVER PEI ET AL.

The Examiner has rejected claims 1-3, 6-13, 16-23, 26-28, 31, and 32 over the disclosure of the compounds NPI-031D and NPI-031E in the reference, asserting that these compounds anticipate the presently claimed invention. Applicants respectfully disagree.

As discussed above, independent claims 2, 8, 18, and 27 do not allow for the R₅ hydroxyl group required by NPI-031D and NPI-031E. Clearly, these claims and all claims dependent thereupon are not anticipated by Pei et al.

With respect to currently pending independent claims 1, 7, 17, and 26, as amended these claims do not allow for heterocyclic groups in the R₁ position as required by NPI-031D. Also,

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independent claims 1, 7, 17, and 26 now contain proviso language specifically stating that R₅ cannot be -OH when R₁, R₂, R₃, R₄, R₆, and R₇ are all H, thereby excluding NPI-031E.

For these reasons, Pei et al. does not anticipate rejected independent claims 1, 2, 7, 8, 17, 18, 26, and 27 or any other claims dependent thereupon. Reconsideration and withdrawal of the rejection are in order and are respectfully requested.

THE REJECTION UNDER 35 U.S.C. §102(B) OVER ITO ET AL.

The Examiner has rejected claims 26-28, 31, and 32 over the disclosure presented in the Abstract and in the material spanning line 54 of column 1 to line 28 of column 2 of Ito et al. The Examiner contends that the compounds depicted in these sections anticipate the presently claimed invention. Applicants respectfully disagree.

Ito et al. discloses a group of isoflavone derivatives having various amino, amido, thio, or carboxy moieties in the R₃ position of the currently claimed compounds. As amended, independent claims 26 and 27 specify that R₃ must be hydrogen. Given that the compounds of the invention cannot contain the various R₃ amino, amido, thio, or carboxy moieties of Ito et al., the reference cannot anticipate the subject matter of claims 26 and 27 or any claims dependent thereupon. Reconsideration and withdrawal of the rejection are in order and are accordingly requested.

THE REJECTION UNDER 35 U.S.C. §102(B) OVER BLAISE ET AL.

The Examiner has rejected claims 26-28, 31, and 32 over the compounds of Formula I and II, as presented on page 1 of the reference. The Examiner contends that these compounds anticipate the presently claimed invention. Applicants respectfully disagree.

The compounds disclosed by Blaise et al. contain C₁₋₃ alkoxy carbonylalkyl moieties in the R₁ position. These moieties are not within the scope of the presently pending claims. Independent claim 26 does not allow any alkoxy carbonylalkyl groups in the R₁ position and independent

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claim 27 permits only C₄₋₆ alkoxy-carbonylalkyl groups. The compounds disclosed by Blaise et al. do not fall within the scope of the independent claims and do not anticipate the independent claims or any claims dependent thereupon. Withdrawal of the rejection is requested.

THE REJECTION UNDER 35 U.S.C. §102(B) OVER JAGDISH ET AL.

The Examiner has rejected claims 26, 27, 29, 31, and 32 over the 24 compounds presented on pages 1097-1098 of the reference. The Examiner contends that these compounds anticipate the presently claimed invention. Applicants respectfully disagree.

Applicants submit that none of the 24 compounds disclosed in the reference fall within the scope of the pending claims for one or more reasons. This can be demonstrated as follows:

1. Compounds 1, 4, 5, 7, 19, 20, and 22 all fail to contain an oxygen atom adjacent to the R₁ position.
2. Compounds 3, 6, 7, 9, 10, 12-17, 20, 22, and 23 all contain substituents other than hydrogen at the R₃ position. As discussed above, independent claims 26 and 27 now require that R₃ be hydrogen, as do all claims dependent thereupon.
3. Claims 3, 5-11, 13, 14, 16-18, and 24 fail to anticipate the pending claims as all of these claims have alkyl moieties in the R₂ position, a substitution that is not allowed in either of the independent claims.
4. Claims 2, 3, 6, 7, 14, 18, and 21, also fail to anticipate the pending claims as they contain substituents other than hydrogen or hydroxide at the R₆ position.

As none of the cited compounds in the reference fall within the scope of the pending claims, the rejection is in error. Reconsideration and withdrawal of the rejection are in order and are requested.

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THE REJECTION UNDER 35. U.S.C. §112, SECOND PARAGRAPH

The Examiner has rejected claims 1-6 and 17-24 for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Specifically, the Examiner asserts that independent claims 1-6 fail to distinctly claim the subject matter that Applicant regards as the invention as the language "inhibiting ALDH-2" does not stand for a specific or meaningful disease. Similarly, claims 17-24 have been rejected for their inclusion of the language "identifying a compound that modulates ALDH-2." Applicants disagree with the Examiner and submit that the rejection is in error.

With respect to both aspects of the rejection, Applicants are unsure exactly what the Examiner finds indistinct about the language "inhibiting..." or "identifying..." The Examiner has supported the rejection by stating that these terms do not stand for a specific or meaningful disease, but Applicants are not aware of any law or regulation requiring that a claim must be drawn to a method of treating a specific disease or condition in order to satisfy the requirements of 35. U.S.C. §112, second paragraph.

If the Examiner was actually attempting to question the utility of inhibiting ALDH-2 or identifying compounds that are capable of modulating ALDH-2, then the rejection should have been raised under 35 U.S.C. §101. In the event that this was what the Examiner intended, Applicants submit the rejection would still be in error. The utility of inhibiting ALDH-2 and compounds that are capable of modulating ALDH-2 is plainly evident giving the teaching of the specification. Applicants further direct the Examiner to U.S. Patent Nos. 5,204,269 and 6,121,010, wherein methods of treating alcohol dependence by inhibiting ALDH-2 are discussed and claimed.

Forth these reasons, Applicants submit that the pending claims fully satisfy the requirements of 35. U.S.C. §112, second paragraph. The rejection is in error and its withdrawal is requested.

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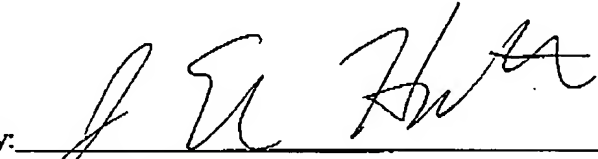
CONCLUSION

For the foregoing reasons, Applicant submits that the claims are in condition for allowance. A Notice of Allowance is requested, and a prompt mailing thereof would be much appreciated.

Should the Examiner have any questions, he is invited to contact the undersigned attorney at (650) 384-8755.

Respectfully submitted,

Date: 2/4/05

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